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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,268	08/10/2001	Stephen Palmer	0455/NP	6603
22930	7590	06/09/2004	EXAMINER	
HOWREY SIMON ARNOLD & WHITE LLP BOX 34 1299 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,268

Applicant(s)

PALMER ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-52 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Claims 27-52 are pending.

Applicants' amendment filed 23 April 2004, which cancels claims 1-26, amends claim 27 and adds claims 28-52, and applicants' request for extension of time of one month have been entered.

Election/restriction

Applicants' election of Group V, claim 27, in the response filed 23 April 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Since claims 28-52 are drawn into the elected invention, i.e., a method of collecting oocytes for in vitro fertilization, claims 28-52 together with the elected claim 27 are under examination to the extent that they are drawn to the elected invention.

Specification/Claim/ Objections

The disclosure is objected to because of the following informalities:

In page 5, line 1, "hCG" should be spelled out in full for the first instance of use. See also page 6, line 5, "PDE".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not describe (i) all phosphodiesterase (PDE) inhibitors have ability of inducing ovulation; the specification only describes and provides working examples for PDE inhibitors named compounds 1-4; and (ii) modulator, which includes inhibitor and stimulator, of cAMP level for inductions of ovulation.

Thus, applicants are not in possession of a method of collecting oocyte for in vitro fertilization comprising administering to a subject a non-polypeptide cAMP level modulator, whereby ovulation is induced, and collecting oocytes from said female. Applicants are in possession of the method of inducing ovulation comprising administering to a subject a PDE specific inhibitor, i.e., compound 1 or 2, or 3 or 4.

There are 11 PDE subtypes; of them, PDE 4 and PDE 7 are cAMP specific (i.e., specifically hydrolyzes cAMP phosphodiester bond) while PED4 is only cAMP specific; By contrast, PDE5 and 6 are cGMP specific (see Table 1 of Travadi, J. N. et al. (2003) *Pediat. Pulmonol.* 36, 529-535). Because (i) structure and function of PDE superfamily is of complexity (see Conti, M. (2000) *Mol. Endocrinol.* 14, 1317-1327) and PDE activity is highly diverse; (ii) the PDE substrates, i.e., cGMP and cAMP involve in distinct cell signaling, and (iii) the current invention is unrelated to modulation of cGMP level in the subject, applicants need to provide written description for inhibitors of the PDE superfamily in order for enablement for the claimed

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method. Moreover, Conti et al. (US Pat. No. 6110471) have shown that the PDE3-specific inhibitor prevents oocytes maturation thereby inhibits ovulation (see the patent claims 1-3 and 14 and columns 3-4), i.e., the PDE3 specific inhibitor has the opposite role in ovulation compared to PDE4 specific inhibitor. This indicates that not all PDE inhibitors have ability of inducing ovulation. Thus, without written description, one cannot know a compound inhibiting a PDE (e.g., PDE3) can elevate a cAMP level; thereby promote ovulation induction. Therefore, applicants are not in possession of the method of inducing ovulation comprising administering to a subject a PDE inhibitor (*a genus*) that encompasses any inhibitors of PDE subtypes, i.e., PDE1 to PDE3 and PDE5 to PDE11.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

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Claims 33-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites "related steroidogenic enzymes"; wherein "related" is unclear as to what is related.

Claim 33 recites "comprising administering to said female an agent..."; the claim does not make it clear as to at which time point, i.e., before, or, after or simultaneously the administering is carried out. See also claims 41 and 46. The dependent claims are also rejected.

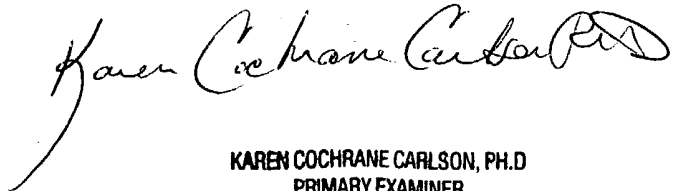
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.
Art Unit 1653, Examiner
May 18, 2004



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER